Appln. No. 09/806,636
AMENDMENT AFTER ALLOWANCE UNDER 37 C.F.R. 1.312
Docket No. FJIN-109

Amendment to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Please amend Claim 30 as follows:

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SD. 2/11/04

Listing of Claims:

1. (Canceled)

2. (Previously presented) The controlled-release oral preparation of esculetin according to claim 28, containing 0.5 to 90 wt % of the gel-forming polymer base.

3. (Original) The controlled-release oral preparation of esculetin according to claim 2, wherein the gel-forming polymer base is hydroxypropylmethylcellulose.

4. (Previously presented) The controlled-release oral preparation of esculetin according to claim 30, containing 0.5 to 50 wt % of the enteric coating base.

5. (Previously presented) The controlled-release oral preparation of esculetin according to claim 4, wherein the enteric coating base is selected from the group consisting of hydroxypropylmethylcellulose acetate succinate, hydroxypropylmethylcellulose phthalate, cellulose acetate phthalate, carboxymethylethylcellulose, and methacrylic acid copolymer.

6. (Previously presented) The controlled-release oral preparation of esculetin according to claim 28, containing 0.5 to 50 wt % of an insoluble coating base.

7. (Previously presented) The controlled-release oral preparation of esculetin according to claim 6, wherein the insoluble coating base is ethylcellulose.

8. (Previously presented) The controlled-release oral preparation of esculetin according to claim 32, comprising 0.5 to 90 wt % of the gel-forming polymer base, and 0.5 to 50 wt % of the enteric coating base and 0.5 to 50 wt % of the insoluble coating base.

9. (Previously presented) The controlled-release oral preparation of esculetin according to claim 28, wherein the release of esculetin or its derivative is controlled so that the concentration of glucuronic acid conjugates in plasma is maintained at 0.5 μmol/L or more for a period of 10 hours or more after administration when the preparation is orally administered to a beagle dog at a dose of 1-100 mg/kg.

10. (Previously presented) The controlled-release oral preparation of esculetin according to claim 28, wherein the release of esculetin is controlled so that the period of time required for the preparation to dissolve 80 wt % of esculetin is 0.5 to 23 hours as determined by the dissolution test according to the paddle method of the Japanese Pharmacopoeia.

11. (Previously presented) The controlled-release oral preparation of esculetin according to claim 2, wherein the release of esculetin or its derivative is controlled so that the concentration of glucuronic acid conjugates in plasma is maintained at 0.5 μmol/L or more for a period of 10 hours or more after administration when the preparation is orally administered to a beagle dog at a dose of 1-100 mg/kg.

12. (Previously presented) The controlled-release oral preparation of esculetin according to claim 3, wherein the release of esculetin or its derivative is controlled so that the concentration of glucuronic acid conjugates in plasma is maintained at 0.5 μmol/L or more for a period of 10 hours or more after administration when the preparation is orally administered to a beagle dog at a dose of 1-100 mg/kg.

13. (Previously presented) The controlled-release oral preparation of esculetin according to claim 4, wherein the release of esculetin or its derivative is controlled so that the concentration of glucuronic acid conjugates in plasma is maintained at 0.5 μmol/L or more for a period of 10 hours or more after administration when the preparation is orally administered to a beagle dog at a dose of 1-100 mg/kg.

14. (Previously presented) The controlled-release oral preparation of esculetin according to claim 5, wherein the release of esculetin or its derivative is controlled so that the concentration of glucuronic acid conjugates in plasma is maintained at 0.5 μmol/L or more for a period of 10 hours or more after administration when the preparation is orally administered to a beagle dog at a dose of 1-100 mg/kg.

15. (Previously presented) The controlled-release oral preparation of esculetin according to claim 6, wherein the release of esculetin or its derivative is controlled so that the concentration of glucuronic acid conjugates in plasma is maintained at 0.5 μmol/L or more for a period of 10 hours or more after administration when the preparation is orally administered to a beagle dog at a dose of 1-100 mg/kg.

16. (Previously presented) The controlled-release oral preparation of esculetin according to claim 7, wherein the release of esculetin or its derivative is controlled so that the concentration of glucuronic acid conjugates in plasma is maintained at 0.5 μmol/L or

more for a period of 10 hours or more after administration when the preparation is orally administered to a beagle dog at a dose of 1-100 mg/kg.

17. (Previously presented) The controlled-release oral preparation of esculetin according to claim 8, wherein the release of esculetin or its derivative is controlled so that the concentration of glucuronic acid conjugates in plasma is maintained at 0.5 μmol/L or more for a period of 10 hours or more after administration when the preparation is orally administered to a beagle dog at a dose of 1-100 mg/kg.

18. (Previously presented) The controlled-release oral preparation of esculetin according to claim 2, wherein the release of esculetin is controlled so that the period of time required for the preparation to dissolve 80 wt % of esculetin is 0.5 to 23 hours as determined by the dissolution test according to the paddle method of the Japanese Pharmacopoeia.

19. (Previously presented) The controlled-release oral preparation of esculetin according to claim 3, wherein the release of esculetin is controlled so that the period of time required for the preparation to dissolve 80 wt % of esculetin is 0.5 to 23 hours as determined by the dissolution test according to the paddle method of the Japanese Pharmacopoeia.

20. (Previously presented) The controlled-release oral preparation of esculetin according to claim 4, wherein the release of esculetin is controlled so that the period of time required for the preparation to dissolve 80 wt % of esculetin is 0.5 to 23 hours as determined by the dissolution test according to the paddle method of the Japanese Pharmacopoeia.

21. (Previously presented) The controlled-release oral preparation of esculetin according to claim 5, wherein the release of esculetin is controlled so that the period of time required for the preparation to dissolve 80 wt % of esculetin is 0.5 to 23 hours as determined by the dissolution test according to the paddle method of the Japanese Pharmacopoeia.

22. (Previously presented) The controlled-release oral preparation of esculetin according to claim 6, wherein the release of esculetin is controlled so that the period of time required for the preparation to dissolve 80 wt % of esculetin is 0.5 to 23 hours as determined by the dissolution test according to the paddle method of the Japanese Pharmacopoeia.

23. (Previously presented) The controlled-release oral preparation of esculetin according to claim 7, wherein the release of esculetin is controlled so that the period of time required for the preparation to dissolve 80 wt % of esculetin is 0.5 to 23 hours as determined by the dissolution test according to the paddle method of the Japanese Pharmacopoeia.

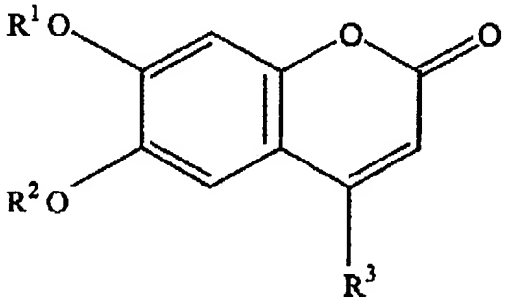
24. (Previously presented) The controlled-release oral preparation of esculetin according to claim 8, wherein the release of esculetin is controlled so that the period of time required for the preparation to dissolve 80 wt % of esculetin is 0.5 to 23 hours as determined by the dissolution test according to the paddle method of the Japanese Pharmacopoeia.

25. (Previously presented) The controlled-release oral preparation according to claim 6, wherein the insoluble coating base is an aminoalkylmethacrylate copolymer.

26. (Previously presented) The controlled-release oral preparation of esculetin according to claim 8, wherein the enteric coating base is selected from the group consisting of hydroxypropylmethylcellulose acetate succinate, hydroxypropylmethylcellulose phthalate, cellulose acetate phthalate, carboxymethylethylcellulose, and methacrylic acid copolymer, and the insoluble coating base is selected from the group consisting of ethylcellulose and aminoalkylmethacrylate copolymer.

27. (Canceled)

28. (Previously presented) A controlled-release oral preparation comprising: a granulated mixture of: a) esculetin, or its derivative shown by the formula (I),



(I)

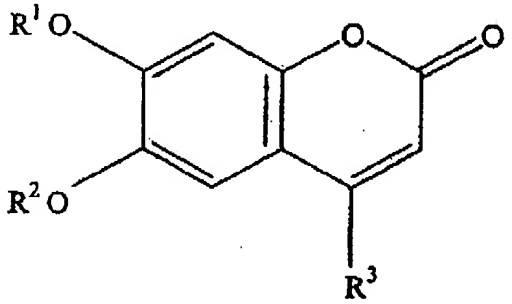
wherein R^1 and R^2 are individually a hydrogen atom or a saturated or unsaturated aliphatic acyl group having 2-25 carbon atoms or a benzoyl group, and R^3 is a hydrogen atom, hydroxyl group, alkyl group, aryl group, or aralkyl group, or a pharmaceutically acceptable salt thereof as an effective component; and b) a gel-forming polymer base; and

an enteric capsule containing the granulated mixture.

29. (Previously presented) The controlled-release oral preparation of esculetin according to claim 28, wherein the enteric capsule comprises an enteric coating base selected from the group consisting of hydroxypropylmethylcellulose acetate succinate, hydroxypropylmethylcellulose phthalate, cellulose acetate phthalate, carboxymethylethylcellulose, and methacrylic acid copolymer.

30. (Currently Amended) A controlled-release oral preparation consisting essentially of:

a tablet ~~comprising~~ consisting essentially of a compressed mixture of: a) esculetin, or its derivative shown by the formula (I),



(I)

wherein R^1 and R^2 are individually a hydrogen atom or a saturated or unsaturated aliphatic acyl group having 2-25 carbon atoms or a benzoyl group, and R^3 is a hydrogen atom, hydroxyl group, alkyl group, aryl group, or aralkyl group, or a pharmaceutically acceptable salt thereof as an effective component; and b) a gel-forming polymer base; and

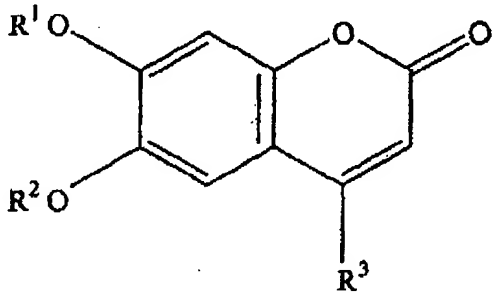
an enteric coating base on the compressed mixture.

31. (Previously presented) The controlled-release oral preparation of esculetin according to claim 30, wherein the enteric coating base is selected from the group consisting of hydroxypropylmethylcellulose acetate succinate,

hydroxypropylmethylcellulose phthalate, cellulose acetate phthalate, carboxymethylethylcellulose, and methacrylic acid copolymer.

32. (Previously presented) A controlled-release oral preparation consisting essentially of:

a tablet consisting essentially of a compressed mixture of: a) esculetin, or its derivative shown by the formula (I),



(I)

wherein R^1 and R^2 are individually a hydrogen atom or a saturated or unsaturated aliphatic acyl group having 2-25 carbon atoms or a benzoyl group, and R^3 is a hydrogen atom, hydroxyl group, alkyl group, aryl group, or aralkyl group, or a pharmaceutically acceptable salt thereof as an effective component; and b) a gel-forming polymer base; and

an enteric coating base on the compressed mixture; and

an insoluble coating base.